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**510(k) SUMMARY
FOR CERAMOPTEC'S
CERALAS DIODE LASER SYSTEMS (MODEL D15)**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

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Name of Device and Name/Address of Sponsor

Ceralas Diode Laser Systems (Model D15)

CeramOptec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical Laser

Predicate Device

CeramOptec Inc.'s Ceralas Diode Laser System (Model D50)

Intended Use

The Ceralas Diode Laser System ("Ceralas D15") is intended to be used for incision, excision, vaporization, hemostasis, and coagulation of soft tissues in open and closed (endoscopic) procedures. The Ceralas D15 is indicated for use in general surgery, urology, gynecology, neurosurgery (hemostasis), gastroenterology, plastic surgery, dermatology (vascular lesions), and otolaryngology (*i.e.*, ear, nose, and throat ("ENT")), including the specific ENT

procedures of tonsillectomy, hemiglossectomy, vocal cord polypectomy, tracheal stenosis, polypectomy, thyroidectomy, neck dissection, and oral cavity lesions.

Technological Characteristics and Substantial Equivalence

The Ceralas D15 utilizes gallium aluminum arsenide semiconductor diodes to generate near-infrared laser radiation. The laser is air cooled with thermoelectric coolers. The exposure mode for the laser is 0 -15 watts, either in a continuous or pulsed delivery mode. The Ceralas D15, like the Ceralas D50 is microprocessor controlled.

The delivery systems for the Ceralas D15 consist of fiber optic cables which are fitted with an SMA-905 connector at the proximal end. The distal ends are available in a variety of configurations, including cleaved/flat or sculpted/shaped (conical, round, and chisel). The fiber optic cables are composed of a quartz fiber core with a coaxially mounted protective sheath. The cables are available with or without handpiece accessories.

The Ceralas D15 has the same intended use, principles of operation, and technological characteristics as the previously cleared predicate laser system. The Ceralas D15 and the Ceralas D50 both employ a semiconductor diode to generate the treatment beam. The Ceralas D15 and D50 are both solid state lasers that emit a beam in the near-infrared region of the electromagnetic spectrum. The wavelength for the Ceralas D15 and D50 is 980 ± 30 nm. Both lasers offer a continuous and pulsed exposure operating mode. They also both use the same laser diode aiming beam with a 670 nm wavelength with an adjustable power output maximum of 4 mW. The only difference between the Ceralas D15 and D50 is the power output; the Ceralas D15 provide 0-15 watts whereas the D50 provides 0-50 watts. This modification does not raise new issues of safety or effectiveness because the cleared laser's power output range encompasses the Ceralas D15's 0-15 power output range.